

AFTATE TRIPLE ANTIBIOTIC- triple antibiotic ointment ointment
Sabel Med LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Triple Antibiotic Ointment

Directions

- Clean the affected area
- Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily
- May be covered with a sterile bandage

Uses first aid to help prevent infection in ■ minor cuts ■ scrapes ■ burns

Stop use and ask a doctor if ■ condition persists or gets worse ■ rash or other allergic reaction develops

Warnings
For external use only

Do not use

- in the eyes
- if you are allergic to any of the ingredients
- over large areas of the body
- longer than 1 week unless directed by a doctor

Ask a doctor before use in case of

- deep puncture wounds ■ animal bites ■ serious burns

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Active Ingredients per gram	Purpose
Bacitracin Zinc 400 units.....	First aid antibiotic
Neomycin Sulfate 5 mg (equivalent to 3.5 mg Neomycin)	First aid antibiotic
Polymyxin B Sulfate 5,000 units.....	First aid antibiotic

Inactive ingredient white petrolatum

Purpose
First aid antibiotic
First aid antibiotic
First aid antibiotic

2 mm BG Area can be extend but after formation of the tube will come on back panel



Net wt 1oz. (28 g)

Original Strength Triple Antibiotic Ointment

NDC 70356-101-01

Infection
Protection for
Burns, Cuts
& Scrapes

• Bacitracin • Neomycin Sulfate • Polymyxin B Sulfate

First Aid Antibiotic Ointment
for minor scrapes, cuts & burns

<p>Drug Facts</p> <p>Active Ingredients per gram</p> <p>Bacitracin Zinc 400 units.....First aid antibiotic Neomycin Sulfate 5 mg (equivalent to 3.5 mg Neomycin)First aid antibiotic Polymyxin B Sulfate 5,000 units.....First aid antibiotic</p> <p>Purpose</p> <p>Stop use and ask a doctor if <input type="checkbox"/> condition persists or gets worse <input type="checkbox"/> rash or other allergic reaction develops Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <p><input type="checkbox"/> Clean the affected area <input type="checkbox"/> Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily <input type="checkbox"/> May be covered with a sterile bandage</p> <p>Other Information <input type="checkbox"/> store at 15°-30°C (59°-86°F) <input type="checkbox"/> avoid excessive heat and humidity</p> <p>Inactive Ingredient white petrolatum Questions? Call toll free 888.5Aftate or 888.523.8283</p> <p>Distributed by: Sabel Med LLC Oldsmar, FL 34677 Aftate™ RetroBrands U.S.A. LLC 2016</p>		<p>Uses first aid to help prevent infection in <input type="checkbox"/> minor cuts <input type="checkbox"/> scrapes <input type="checkbox"/> burns</p> <p>Warnings For external use only</p> <p>Do not use</p> <ul style="list-style-type: none"> <input type="checkbox"/> in the eyes <input type="checkbox"/> if you are allergic to any of the ingredients <input type="checkbox"/> over large areas of the body <input type="checkbox"/> longer than 1 week unless directed by a doctor <p>Ask a doctor before use in case of</p> <ul style="list-style-type: none"> <input type="checkbox"/> deep puncture wounds <input type="checkbox"/> animal bites <input type="checkbox"/> serious burns
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5mm

Retain carton for important product information
 Made in India
 MH/DRUGS/KD-180

AFTATE TRIPLE ANTIBIOTIC

triple antibiotic ointment ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70356-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g
BACITRACIN ZINC (UNII: 89Y4M234ES) (Bacitracin - UNII:58H6RWO52I)	Bacitracin	400 [iU] in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70356-101-01	28 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2016	
2	NDC:70356-101-05	14 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2016	
3	NDC:70356-101-33	9.4 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	05/01/2016	

Labeler - Sabel Med LLC (091476000)

Revised: 4/2016

Sabel Med LLC